

REMARKS

Claims 1-7, 9, 11, 16, 17, 19, 22, 26, and 57-61 are currently pending in this application.

The Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

I. Assertion that SEQ ID NO:1 is a Human Cysteinyl Leukotriene Receptor

The specification explicitly asserts that SEQ ID NO:1 is a human cysteinyl leukotriene receptor. *See U.S. 2004-0220092, paragraph [0339], TABLE 2.* However, the Examiner contends that “Applicant is factually in error” in presenting the results in TABLE 2 as an explicit assertion that SEQ ID NO:1 is a human cysteinyl leukotriene receptor, stating:

Table 2 of the instant specification expressly states that the **probability** of SEQ ID NO:1 being a cysteinyl leukotriene receptor is ‘0’. In describing the data presented in Table 2 of the instant specification the text on page 25 therein states that ‘Column 4 shows the **probability score** for the match between each polypeptide and its GenBank homolog.’

The Applicants respectfully point out that the Examiner is confusing the meaning of “probability” with the meaning of “probability score” as used in TABLE 2. A BLAST probability score “indicates the probability of obtaining the observed polypeptide sequence alignment **by chance.**” *See U.S. 2004-0220092, paragraph [0130] (emphasis added).* Therefore, a low probability score is indicative of a low probability of having obtained a match by chance. A probability score of zero (0) means that there is zero probability of having obtained the match by chance. As such, the results in TABLE 2 indicate that there is **zero probability** of having obtained a match between SEQ ID NO:1 and human cysteinyl leukotriene receptor **by chance.** Because one cannot obtain a more significant result, this is an explicit assertion that SEQ ID NO:1 is a human cysteinyl leukotriene receptor.

With respect to TABLE 3, the Examiner has indicated that the phrase “cysteinyl leukotriene receptor” does not appear. However, TABLE 3 indicates that SEQ ID NO:1 includes “Signature Sequences, Domains and Motifs,” which are characteristic of cysteinyl leukotriene receptors. *See id.* at paragraph [0340], TABLE 3. Therefore, the results in TABLE 3 support the explicit assertion in TABLE 2 that SEQ ID NO:1 is a human cysteinyl leukotriene receptor.

II. Objection – 35 U.S.C. § 132, “New Matter”

The amendment filed on July 13, 2005 was objected to for allegedly introducing new matter into the disclosure. In particular, the Title, which recites “HUMAN CYSTEINYL LEUKOTRIENE RECEPTORS,” and the claim limitation “wherein the polypeptide has cysteinyl leukotriene receptor activity” are alleged to be “new matter.” As indicated above, the specification explicitly asserts that SEQ ID NO:1 is a human cysteinyl leukotriene receptor. Therefore, the recitation of “HUMAN CYSTEINYL LEUKOTRIENE RECEPTORS” in the Title and the recitation of “wherein the polypeptide has cysteinyl leukotriene receptor activity” in the claims are not “new matter.” Withdrawal of this ground for objection is requested.

III. Rejection – 35 U.S.C. § 101, “Utility”

Claims 1-7, 9, 11, 16, 17, 19, 22, 26, and 57-61 stand rejected under 35 U.S.C. § 101, allegedly “because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility.” The Applicants respectfully traverse the rejection.

As indicated above, the specification explicitly asserts that SEQ ID NO:1 is a human cysteinyl leukotriene receptor. Others have confirmed that SEQ ID NO:1 is a cysteinyl leukotriene receptor, referred to as “human cysteinyl leukotriene 2 receptor.” *See, e.g.,* Heise *et al., Characterization of the Human Cysteinyl Leukotriene 2 Receptor,* J. BIOL. CHEM. (September 2000), Vol. 275, No. 39, pp 30531-30536, [hereinafter “Heise”] (copy previously provided). Heise recognizes the utility of human cysteinyl leukotriene receptors and indicates that cysteinyl leukotriene receptors mediate contractile and inflammatory actions of cysteinyl leukotriene ligands. The claimed subject matter is related to SEQ ID NO:1, which is asserted

to be a human cysteinyl leukotriene receptor. Therefore, the claimed subject matter has a well known or a “specific and substantial credible utility.” Withdrawal of this ground for rejection is requested.

IV. Rejection – 35 U.S.C. § 112, first paragraph, “Enablement”

Claims 1-7, 9, 11, 16, 17, 19, 22, 26, and 57-61 stand rejected under 35 U.S.C. § 112, first paragraph, allegedly “as failing to adequately teach how to use the invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.” For the reasons stated above with respect to rejection under 35 U.S.C. § 101, the Applicants respectfully contend that the specification adequately teaches how to make and use the claimed invention. Withdrawal of this ground for rejection is requested.

V. Rejection – 35 U.S.C. § 112, first paragraph, “Written Description”

Claims 1- 7, 9, 11, 16, 17, 19, 22, 26, and 57-61 stand rejected under 35 U.S.C. § 112, first paragraph, allegedly “as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” In particular, the Examiner asserts that the application does not “provided a written description of a polypeptide having the amino acid sequence presented in SEQ ID NO:1 and ‘cysteinyl leukotriene activity.’” Further, the Examiner asserts that “the phrase ‘cysteinyl leukotriene receptor activity’ is without support in the instant application and a relationship between this activity and SEQ ID NO:1 is a new inventive concept.” The Applicants traverse the rejection.

As indicated above, the specification explicitly asserts that SEQ ID NO:1 is a human cysteinyl leukotriene receptor. Therefore, a polypeptide of SEQ ID NO:1 having cysteinyl leukotriene receptor activity is disclosed in the specification and is not a new inventive concept without support in the specification. Withdrawal of this ground for rejection is requested.

VI. Rejection – 35 U.S.C. § 102, “Takasaki et al.”

Claims 1-7, 9, 11, 16, 17, 19, 22, 26 and 57-61 stand rejected under 35 U.S.C. § 102(a) allegedly “as being clearly anticipated by the Takasaki et al. publication (B.B.R.C. 274(2):316-322, 02 Aug. 2000)” [hereinafter Takasaki publication]. The Applicants traverse the rejection.

The present application claims the benefit of priority of U.S. provisional application no. 60/199,084, filed on April 20, 2000, [hereinafter “the ‘084 application”] (copy previously provided). The filing date of the ‘084 application predates the Takasaki publication. However, the Examiner contends that the ‘084 application does not satisfy the requirements of 35 U.S.C. § 112 with respect to the claimed subject matter. The Applicants respectfully disagree.

The ‘084 application includes substantially similar disclosure as the present application with respect to the pending claims. For example, the ‘084 application discloses SEQ ID NO:1 and SEQ ID NO:7 (*i.e.*, SEQ ID NO:1 and SEQ ID NO:3, respectively). In addition, the ‘084 application explicitly asserts that SEQ ID NO:1 is a cysteinyl leukotriene receptor. At TABLE 2, the ‘084 application indicates that the BLAST probability score for obtaining a match between SEQ ID NO:1 and “Cysteinyl leukotriene LTD4 receptor [Homo sapiens]” is 2.2×10^{-54} . As such, the results in TABLE 2 indicate that there is 2.2×10^{-54} probability of having obtained a match between SEQ ID NO:1 and the human cysteinyl leukotriene receptor by chance. Because this is a highly significant result, this is an explicit assertion that SEQ ID NO:1 is a human cysteinyl leukotriene receptor.

Therefore, the ‘084 application fully supports the presently claimed subject matter under 35 U.S.C. § 112. For these reasons, the pending claims are entitled to a priority date at least as of the filing date of the ‘084 application (*i.e.*, April 20, 2000), which predates the Takasaki publication. As such, withdrawal of the rejection is requested.

VII. Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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